UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	1:06-MD-1789-JFK
This Document Relates to: Louise H. Maley v. Merck & Co., Inc. Case No. 1:06-cv-04110-JFK	**OPINION & ORDER**

APPEARANCES:

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JOHN F. KEENAN, United States District Judge[1]:

This case was selected by Merck Sharp & Dohme Corporation ("Merck" or "Defendant") as a bellwether case in this multi-

[1] To the extent any sealed material is discussed in this opinion, the information is hereby unsealed in light of the strong presumption of public access.

district products liability litigation concerning the osteoporosis drug Fosamax. Before the Court is defendant Merck's motion for summary judgment seeking the dismissal of all claims filed by plaintiff Louise H. Maley ("Maley" or "Plaintiff"). For the following reasons, Merck's motion is denied.

I. BACKGROUND

A. Fosamax and ONJ[2]

Fosamax is an oral bisphosphonate manufactured by Merck for the treatment of osteoporosis. Plaintiff and her experts contend that Merck has long known of studies and reports linking bisphosphonate use with the development of osteonecrosis of the jaw ("ONJ"), a condition characterized by exposed necrotic bone. Merck began warning consumers of a link between Fosamax and ONJ in July 2005, when it made the following FDA-approved addition to Fosamax's label:

> Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis.

[2] The Court provides information regarding Fosamax only to the extent that it is relevant to the instant motion. For further discussion about the drug, see the Court's ruling on the parties' Daubert motions. In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164 (S.D.N.Y. 2009).

(Def. Ex. 24.)

In 2006, the American Association of Oral and Maxillofacial Surgeons ("AAOMS") issued a position paper on bisphosphonate-related osteonecrosis of the jaw ("BRONJ") — the subset of ONJ injuries caused by bisphosphonate use. The position paper was developed by a task force of highly regarded clinicians, epidemiologists, and other researchers, who analyzed the existing literature and clinical observations of its members to provide perspectives on the risk of developing BRONJ and guidance to clinicians on diagnosing, treating, and preventing the condition. In the position paper, the AAOMS adopted a working definition of BRONJ, under which a patient is considered to have the condition if the following three characteristics are present: (1) current or previous use of a bisphosphonate; (2) exposed, necrotic bone in the maxillofacial region for more than eight weeks; and (3) no history of radiation therapy to the jaw. The AAOMS further classified the condition as stage one, two, or three, depending on the severity and type of the patient's symptoms. The experts on the issue of general causation in this multi-district litigation have used the same or similar definition. See, e.g., Marx Report, Def. Ex. 1, at 1 ("[B]isphosphonate-induced osteonecrosis of the jaws refers to a condition characterized by exposure of bone in the mandible or

maxilla persisting for more than 8 weeks . . . ."); Goss Report, Def. Ex. 11, at 4 (including the presence of exposed bone that fails to heal within six weeks in his working definition of ONJ caused by bisphosphonate use).

In late 2008, the AAOMS task force reconvened to review the research on BRONJ conducted after the release of its 2006 position paper and to make any necessary updates. As a result, in January 2009, the AAOMS released an updated position paper. It maintained the same working definition of BRONJ, which includes a finding of exposed necrotic bone that persists for more than eight weeks. The staging system was amended, though, to include stage zero BRONJ, which includes patients who have been treated with a bisphosphonate with no clinical evidence of necrotic bone, but present with other non-specific symptoms or clinical and radiographic findings. (Mayer Decl. in Support of Daubert Motion, Ex. 42, at 10.)

B. Maley's Condition and the Initial Diagnosis

Maley was prescribed Fosamax by Dr. Dennis Lawton ("Dr. Lawton") beginning in January 1998. Dr. Lawton testified at deposition that he receives yearly updates to the Physician's Desk Reference ("PDR"), a published compilation of manufacturers' prescribing information, and generally keeps up to date on the medications he prescribes. Dr. Lawton first

became aware of an alleged risk between Fosamax and ONJ in 2005. Dr. Lawton testified that despite this risk, he: (1) continues to prescribe Fosamax to patients; (2) does not inform these patients of the risk of developing ONJ; and (3) has never recommended that a patient take a "drug holiday" from Fosamax.

In March 2004, Ms. Maley began having severe aching pain in the upper-right side of her jaw. She had two dental extractions and was treated with Trileptal, an anti-convulsant. Her condition improved for several months following the dental extractions, but it again worsened in 2005, while she was still taking Trileptal. She described having "bad attacks" of "stabbing" pain in her jaw, extending through her forehead, which would last for hours at a time. (Def. Ex. 4.)

Maley's medical records indicate that she saw an array of doctors because of her jaw pain, including five different dentists, none of whom appear to have been able to diagnose her condition. In September 2005, Maley was referred to an endodontist, Dr. William Adams ("Dr. Adams"), to examine her jaw. Dr. Adams conducted exploratory surgery in Maley's jaw and performed a biopsy on a bone sample from her jaw. Dr. Adams found "chronically inflamed granulation," which he described for a layperson as inflammation in her jaw "which should not be there." (Adams Dep., Def. Ex. 9, at 145:15–19.) This led him to

diagnose Maley with neuralgia-inducing cavitational osteonecrosis ("NICO"). According to Dr. Adams, NICO occurs when small areas of bone in the jaw develop cavitations and die, causing the patient to suffer pain.

Dr. Adams treated Maley's condition by surgically debriding the "broken down" area of her jaw, and then grafting the voided area with platelet-rich plasma and demineralized freeze-dried bone. (Id. at 135:4 – 136:21.) Maley continued to experience pain in her jaw after the treatment.

In March 2006, Maley was directed to stop taking Fosamax by a different physician, Dr. Phillipsen, for a reason unrelated to her alleged jaw injury. Prior to receiving this advice, Maley regularly filled her Fosamax prescription but for a few occasions. She has not taken it since.

In June 2006, Maley also began feeling pain in the lower-right area of her jaw. She returned to Dr. Adams, who again diagnosed her with NICO and treated her in the same fashion as he did the prior year. Maley continued to have pain after the second surgery. She generally is pleased with the result of the treatments, though, testifying at her deposition that Dr. Adams "has worked wonders with [her]." (Maley Dep., Def. Ex. 3, at 302:9-16.)

C. Opinions Regarding Maley's Injury

Dr. Adams considers himself an expert on NICO. He has been on the faculty of the Indiana University School of Dentistry since 1974. He has published articles on NICO and has lectured on the topic. Although NICO and ONJ both include the word "osteonecrosis," Dr. Adams explained at his deposition that they are "absolutely" different diseases, which "look different microscopically," "behave extremely different clinically," and, unlike ONJ, NICO is not characterized by exposed bone. (Adams Dep., Def. Ex. 9, at 109:22 - 110:10.) In addition, Dr. Adams is not aware of any evidence linking bisphosphonates to NICO.

Plaintiff does not allege to have developed NICO; rather, she claims to have developed ONJ from her nearly eight years of Fosamax use. Plaintiff refutes Dr. Adams's diagnosis of her injury as NICO, maintaining that it is not a generally accepted condition in the medical community. Dr. Robert E. Marx ("Dr. Marx")[3] submitted an affidavit on Maley's behalf, in which he explains that NICO was first proposed as a cause of oral and maxillofacial pain in the 1970's. According to Dr. Marx, however, it was later accepted in the field that the "cavitations" perceived by dentists in patients they diagnosed

[3] The Court already has found Dr. Marx qualified to serve as an expert in this matter. In re Fosamax, 645 F. Supp. 2d 164, 176 (S.D.N.Y. 2009).

with NICO actually are normal marrow spaces in the jaw that do not cause pain. Dr. Marx notes: "[T]he vast majority of dental professionals, including the majority of Oral and Maxillofacial Surgeons, do not accept NICO as a pathological condition or as a diagnosis." (Pl. Ex. F ¶ 13.) "Moreover, no oral pathology textbooks other than the one edited by the proponents of NICO recognize NICO for inclusion in their text and no association or society of medicine or dentistry recognize NICO as a real disease." (Id.) Dr. Marx shares this opinion, stating that "scientific research fails to support the view that NICO is a distinct medical or dental condition." (Id. ¶ 14.)

Maley has designated Dr. Rand Redfern ("Dr. Redfern") as an expert in this case with regard to specific causation. Dr. Redfern never personally examined Maley. He is a dentist specializing in oralfacial pain and maxillofacial radiology. Dr. Redfern has been a dentist for thirty-six years and currently practices in Colorado Springs, Colorado. Dr. Redfern never has researched personally the link between bisphosphonates and ONJ. He does keep informed on the research and other developments on the issue by reading articles from medical journals and other publications, however, and also personally has treated roughly a dozen patients that he has diagnosed with BRONJ. Dr. Redfern has made several academic presentations on

the topic of BRONJ.

Based on a review of Maley's medical records, Dr. Redfern opines "to a reasonable degree of medical probability and certainty" that Maley developed ONJ from using Fosamax. (Pl. Ex. A.) Dr. Redfern concedes that there is no indication in Maley's medical records that she had exposed bone. He also acknowledged that a patient can develop ONJ absent bisphosphonate use. He explained at his deposition that, although there was no finding of exposed dead bone, the pathology report included several findings, including "fatty bone marrow" and "prominent resting lines," which he believes evidence that Plaintiff's jawbone was degenerating. (Redfern Dep., Def. Ex. 21, at 36-37.) Moreover, the inefficacy of several standard courses of treatment, including antibiotics and surgical debridement, allowed him to rule out other possible causes of Plaintiff's injury. Dr. Redfern agreed with Dr. Marx that Plaintiff does not have NICO, noting the lack of consensus in the dental community regarding the legitimacy of the condition.

II. DISCUSSION

The Complaint in this action initially asserted strict liability claims of failure to warn and design defect, negligence, and breach of express and implied warranties. As a federal court sitting in diversity, we apply state substantive

law and federal procedural law. The parties agree that Indiana law governs this matter as Plaintiff is an Indiana resident, was prescribed Fosamax in Indiana, and was treated for her alleged injuries there. It follows, then, that the Indiana Product Liability Act ("IPLA") applies. See Ind. Code § 34-20-1-1 ("This article governs all actions that are brought by a user or consumer against a manufacturer for physical harm caused by a product regardless of the substantive legal theory or theories upon which the action is brought.").

To succeed on a products liability claim under the IPLA, Plaintiff must establish that: "(1) the seller is engaged in the business of selling the product that caused the injury; (2) the product was defective and unreasonably dangerous; (3) the defect existed at the time the product left the defendant's control; (4) the product was expected to and did reach the consumer without substantial change in its condition; and (5) the defective product was the proximate cause of plaintiff's injuries." Ritchie v. Glidden Co., 242 F.3d 713, 720 (7th Cir. 2001). A product is deemed "defective" only if plaintiff establishes a manufacturing defect, design defect, or a failure to warn. Ind. Code § 34-20-40-1 and -2; see Moss v. Crossman Corp., 136 F.3d 1169, 1171 (7th Cir. 1998).

Merck moves for summary judgment, arguing that Plaintiff's

asserted causes of action fail as a matter of law under the IPLA. Plaintiff does not contest summary judgment to the extent Merck seeks dismissal of causes of action other than the negligence claim based on a failure to warn. The strict liability and warranty claims, therefore, are dismissed.

Merck contends that the negligent failure to warn claim should be dismissed as well. It attacks Plaintiff's case on causation grounds on several fronts.

A. Standard of Review

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). A genuine issue of fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The moving party bears the burden of demonstrating that summary judgment is appropriate. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). In determining whether there is a genuine issue as to any material fact, "the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Liberty Lobby, 477 U.S. at 255. "[I]t ordinarily is sufficient for the movant to

point to a lack of evidence to go to the trier of fact on an essential element of the nonmovant's claim." Cordiano v. Metacon Gun Club, Inc., 575 F.3d 199, 204 (2d Cir. 2009). Where the moving party meets that burden, the opposing party must come forward with specific admissible evidence demonstrating the existence of a genuine dispute of material fact. Celotex, 477 U.S. at 322-23.

B. Negligent Failure to Warn

Merck's arguments on the instant motion for summary judgment are limited to the issue of causation.

To prove causation on her failure to warn claim under Indiana law, Plaintiff must establish both that: (1) the inadequate warning was a substantial cause of Plaintiff's ingestion of Fosamax; and (2) the danger that made the warning inadequate was the same danger that materialized and caused her injury. See Kovach v. Caligor Midwest, 913 N.E.2d 193, 199 (Ind. 2009) (holding that to prove causation, plaintiff must "establish that a warning would have been read and obeyed" and "that the defect in fact caused the plaintiff's injury"); Ortho Pharms. Corp. v. Chapman, 388 N.E.2d 541, 555 (Ind. Ct. App. 1979) ("The first question is whether the defendant's failure to adequately warn was a substantial cause of the plaintiff's ingestion of the defendant's [product]. The second question is

whether such ingestion was a substantial cause of the injury suffered."). Causation is typically an issue of fact, "unless only one conclusion can be drawn from the facts." Ritchie, 242 F.3d at 725. Merck argues that there is no issue of material fact to be submitted to a jury on either prong of the causation inquiry.

1. Merck's Failure to Warn as the Cause of Plaintiff's Taking of Fosamax

Under the learned intermediary doctrine, the duty to warn runs from the drug manufacturer to the treating physician — not the patient. See Ortho, 388 N.E.2d at 552-53. The causation inquiry therefore focuses on the hypothetical actions of Plaintiff's treating physician had he been provided a proper warning. Maley has not presented any evidence in opposition to Merck's motion which tends to show that her treating physician, Dr. Lawton, would have taken a different course of treatment by not prescribing her Fosamax had he been adequately warned. The complete lack of evidence would prove fatal under the law of some states where Plaintiff has the burden of production on this aspect of causation. See In re Fosamax Prods. Liab. Litig., 647 F. Supp. 2d 265, 277-82 (S.D.N.Y. 2009) (applying Florida law); In re Fosamax, 06 MDL 1789, 06 Civ. 7631, 2009 WL 4042769, at *4 (S.D.N.Y. Nov. 23, 2009) (applying Mississippi law).

Under Indiana law, however, a plaintiff alleging a failure

to warn claim has the benefit of a "heeding presumption," meaning that there is a presumption that an adequate warning would have been read and heeded. See Kovach, 913 N.E.2d at 199 (noting that the "read-and-heed" presumption establishes "that a warning would have been read and obeyed"); Ortho, 388 N.E.2d at 555 n.12 ("Such a presumption works in favor of the manufacturer when an adequate warning is present. Where there is no warning, as in this case, however, the presumption that the user would have read an adequate warning works in favor of the plaintiff user." (quoting Restatement (Second) of Torts § 402(A) cmt. J (1965))).

The heeding presumption is not determinative on the issue of proximate cause, as it may be rebutted with evidence that an adequate warning would not have been heeded. Ortho, 388 N.E.2d at 555 n.12; see also Adesina v. Aladan Corp., 438 F. Supp. 2d 329, 338 (S.D.N.Y. 2006) ("A defendant may rebut this presumption by introducing specific facts showing that the warning would have been futile." (quotation omitted)) (applying New York law). A party seeking summary judgment on the issue of proximate cause faces a difficult burden as this generally is an issue of fact. Merck must establish that the only reasonable conclusion the trier of fact could draw from the record evidence is that Plaintiff's treating physician would not have changed

his course of treatment had he been adequately warned. See Kovach, 913 N.E.2d at 198 ("[W]here reasonable minds cannot disagree as to [proximate causation], the issue may become a question of law for the court."); Boerner v. Brown & Williamson Tobacco Corp., 260 F.3d 837, 844-45 (8th Cir. 2001) (holding that summary judgment is proper despite the heeding presumption "[i]f the defendant produces evidence so strong that it would necessarily persuade any reasonable trier of fact that an adequate warning would have been futile"); Pavlik v. Lane Ltd./Tobacco Exps. Int'l, 135 F.3d 876, 884 (3d Cir. 1998) ("While [defendant] need only produce evidence sufficient to support a finding contrary to the presumed fact to rebut the [heeding presumption] at trial, to satisfy Rule 56 the record must show that a reasonable fact finder would be bound to find [contrary to the presumed fact.]" (citation omitted)).

Here, Merck points to Dr. Lawton's deposition testimony, where he stated that even after he learned of the association between bisphosphonates and ONJ in 2005, he continues to prescribe Fosamax to some patients and generally does not warn them of that risk.

Merck is not entitled to summary judgment based on this evidence. Dr. Lawton's testimony establishes that he prescribes Fosamax to some of his patients despite the risk of ONJ, but

this falls short of establishing that he would not have changed any of his earlier decisions to prescribe Fosamax to a patient had he known of that risk. Doctors determine a course of treatment on a patient-by-patient basis, and it is quite possible that although Dr. Lawton still prescribes Fosamax to some patients, he chooses an alternate course of treatment for others. Having been provided no other details regarding to whom, or under what circumstances, Dr. Lawton continues to prescribe Fosamax, it is not unreasonable to conclude that he could have chosen a different course of treatment for Plaintiff had he been adequately warned. Drawing all reasonable inferences in favor of Plaintiff, the non-movant, this remains an issue of fact to be determined by a jury.

2. Fosamax as the Cause of Plaintiff's Injury

The Court, in its decision on the parties' Daubert motions, already has found admissible expert testimony of witnesses who will opine at Maley's trial that Fosamax generally can cause ONJ.[4] See In re Fosamax, 645 F. Supp. 2d 164, 187-89 (S.D.N.Y. 2009) (admitting the expert opinions of Drs. Marx, Goss, Hellstein, and Etminan). The focus of the present motion,

[4] As discussed earlier, Plaintiff has never claimed to have developed NICO in the instant litigation. Her claim is that she developed ONJ, and that Merck was negligent in failing to warn of the risk of developing ONJ. The Court need not address whether NICO is a scientifically-accepted condition or whether it can be caused by bisphosphonate use.

therefore, is whether Fosamax caused Plaintiff's injury in this instance – i.e., specific causation.

Merck argues that Plaintiff's claim fails as a matter of law because Dr. Redfern's opinion – the only evidence presented by Plaintiff regarding specific causation – is conclusory, based on methodology that is not scientifically valid, and is thus inadmissible under Rule 702 and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993). Further, according to Merck, even if the Court admits Dr. Redfern's testimony, Plaintiff's claim fails because Dr. Redfern conceded that there is no evidence that Plaintiff had exposed necrotic bone in her jaw, a prerequisite to a diagnosis of BRONJ in the AAOMS position paper and the reports of the general causation experts in this matter.

a. Admissibility of Dr. Redfern's Opinion

Rule 702 specifies that a witness may be qualified as an expert "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Qualification as an expert is viewed liberally and may be based on "a broad range of knowledge, skills, and training." In re TMI Litig., 193 F.3d 613, 664 (3d Cir. 1999); In re Methyl Tertiary Butyl Ether ("MTBE") Prods. Liab. Litig., No 1-00-1898, 2008 WL 1971538, at *5 (S.D.N.Y. May 7, 2008) (stating that "[c]ourts within the Second Circuit have liberally construed expert qualification

requirements" (quotation omitted)). However, the expert must have relevant experience and qualifications such that whatever opinion he will ultimately express would not be speculative. See Quintilla v. Komori Am. Corp., No. 04 Civ. 5227, 2007 WL 1309539 (E.D.N.Y. May 4, 2007); Barban v. Rheem Textile Sys., Inc., No. 01 Civ. 8475, 2005 WL 387660 (E.D.N.Y. Feb. 11, 2005).

Not only must the witness qualify as an expert, but his testimony must be scientifically valid. The Daubert Court interpreted Rule 702 to require district courts to act as gatekeepers by ensuring that expert scientific testimony "both rests on a reliable foundation and is relevant to the task at hand." Daubert, 509 U.S. at 597. This requires "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93. Daubert set forth a non-exclusive list of factors that courts might consider in gauging the scientific validity of proffered testimony. Id. at 593-95. These factors include: (1) whether the theory has been tested; (2) whether the theory has been subjected to peer review and publication; (3) the known or potential rate of error and whether standards and controls exist and have been maintained with respect to the technique; and (4) the general acceptance of the methodology in

the scientific community. Id.

In its Daubert analysis, the Court must "undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand." Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 267 (2d Cir. 2002). Although the Court in Daubert focused on an expert's methodology rather than his conclusions, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997). Only serious flaws in reasoning will warrant exclusion. "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process — competing expert testimony and active cross-examination — rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998) (quoting Daubert, 509 U.S. at 596); Olin Corp. v. Certain Underwriters at Lloyd's London, 468 F.3d 120, 134 (2d Cir. 2006) ("[Cross-examination] is an appropriate way of attacking weak expert testimony, rather than complete exclusion.").

It is clear from the record evidence that Dr. Redfern has specialized knowledge and is adequately qualified under Rule 702 to testify in this matter. He has practiced dentistry for over 30 years; he specializes in oralfacial pain and maxillofacial radiology; he keeps up to date with the developments in research regarding BRONJ and has given presentations on the issue; he also has practical experience in that he has treated many patients that he believes developed ONJ from a bisphosphonate.

The overwhelming focus of Merck's argument in support of its motion for summary judgment is whether Dr. Redfern used a scientifically valid methodology in concluding that Maley developed BRONJ from Fosamax. Merck initially argued that Dr. Redfern's testimony is inadmissible because his methodology was conclusory and failed to address the other potential factors that could have caused Plaintiff's injury. This argument is undercut by Dr. Redfern's testimony at the Daubert hearing ordered by the Court. Dr. Redfern explained that he reached his conclusion that Fosamax caused Plaintiff's injury through the use of a differential diagnosis. "[D]ifferential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the 'most likely' cause of a set of signs and symptoms from a list of possible causes." Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254 (2d Cir. 2005)

(quotation omitted). "[L]ike any process of elimination, it assumes that the final, suspected 'cause' remaining after this process of elimination must actually be capable of causing the injury." Id. (quotation omitted).

"While an expert need not rule out every potential cause in order to satisfy Daubert, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors identified by the defendant." Israel v. Spring Indus., No. 98 CV 5106, 2006 WL 3196956, at *5 (E.D.N.Y. Nov. 3, 2006); see also Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 202 (4th Cir. 2001) ("[I]f an expert utterly fails to consider alternative causes or fails to offer an explanation for why the proffered alternative cause was not the sole cause, a district court is justified in excluding the expert's testimony.").

Dr. Redfern reached his conclusion by reviewing the records of Plaintiff's treating physicians, who went through an extensive process of attempting to rule out various causes of Plaintiff's persisting jaw condition. From their records, including the inefficacy of standard courses of treatment such as antibiotics, and a pathology report with findings consistent with dead or dying bone, Dr. Redfern was able to rule out the other potential causes for her injury, including trigeminal

neuralgia, metastasis of breast cancer, bone tumors or cysts, fractures, and periodontal problems, and deduce that Plaintiff suffered from BRONJ caused by her Fosamax use.

On cross-examination, Merck focused on what it viewed as fatal flaws in the reasoning and methodology behind Dr. Redfern's conclusions. Merck maintains, for example, that Dr. Redfern needed an additional MRI, which was never conduced, to diagnose Plaintiff with stage zero BRONJ because the existing radiology was not diagnostic; that he admitted on cross-examination that he did not recall reviewing a specific medical record which, according to Merck, cuts against his conclusion that Plaintiff did not have trigeminal neuralgia; and that Dr. Redfern's testimony regarding the exact mechanism by which bisphosphonates allegedly cause ONJ does not fully comport with the opinions of the general causation experts. Merck's objections to the soundness of Dr. Redfern's opinion are noted, but they do not lead the Court to conclude that there is such a large analytical gap between the medical records and his conclusion as to warrant exclusion. Cross-examination is the appropriate method for Merck to expose what it believes are flaws in Dr. Redfern's reasoning.

Dr. Redfern's expert testimony is admissible on the issue of specific causation.

b. Stage Zero BRONJ

The Court does not agree with Merck's position that Plaintiff's claim fails as a matter of law without evidence that she had exposed necrotic bone in her jaw.

The BRONJ position paper was updated over one year ago based on new research in the field to include stage zero BRONJ, which does not require exposed necrotic bone. The AAOMS task force is comprised of highly regarded experts in this field, including Dr. Marx, one of Plaintiff's experts on general causation. Another expert on general causation in this matter, Dr. Hellstein, testified that he regards the AAOMS as the "leading body" in oral surgery (Sept. 16, 2009 Daubert Hr'g Tr. at 357.); that the task force that drafted its position paper on BRONJ was "a panel of careful and experienced researches in the field" (Id. at 361.); and that he has adopted the staging system set forth in paper. (Id. at 352-53.) Merck seemingly ignores that, for those reasons, this Court already has recognized stage zero BRONJ. See In re Fosamax, 645 F. Supp. 2d 164, 171 (S.D.N.Y. 2009) (recognizing "stage zero" as a sub-class of patients with BRONJ); In re Fosamax, 647 F. Supp. 2d at 276 (finding that plaintiff developed ONJ no later than September 2003 because an expert testified that, in his opinion, plaintiff's symptoms as of that time could have been stage zero

BRONJ).

Merck has not presented the Court any authority or expert that disagrees with the AAOMS's position that stage zero BRONJ should be considered an ONJ injury. Nor does Merck cite any authority that disputes that bisphosphonates can cause this less advanced form of the injury. Rather, Merck attempts to play on an inconsistency within the definition of BRONJ promulgated by the AAOMS and the experts in this matter. Specifically, Merck argues that BRONJ by definition requires exposed necrotic bone, so stage zero, which is not characterized by exposed necrotic bone, cannot be a recognized form of the condition. The AAOMS definition of BRONJ first set forth in 2006 must be read in light of the 2009 amendments. The Court is mindful of the apparent inconsistency of including stage zero into the spectrum of BRONJ injuries while that spectrum remains defined by exposed necrotic bone. It is important to note, though, that stage zero BRONJ is not merely a sub-clinical injury of those at risk of later developing BRONJ, but rather includes a class of patients — including Plaintiff — who present real symptoms, including aching jaw pain. Although the definitional inconsistency is troubling, it also seems highly dubious to the Court that the AAOMS would include stage zero within the spectrum of BRONJ injuries if it were something other than a less severe form of

the injury.

Moreover, Merck's position that stage zero BRONJ is merely a predecessor stage to the actual injury is further belied by the statement in the AAOMS position paper that the frequency at which stage zero patients advance to more serious stages of the disease currently is unknown. (Mayer Decl., Ex. 42, at 10.)

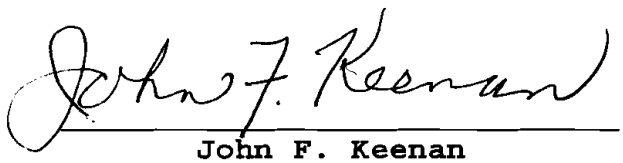
Plaintiff's claim does not fail as a matter of law from a lack of evidence of exposed necrotic bone. Specific causation remains a material issue of fact for the jury, and therefore Merck's motion is denied.

III. CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment on Plaintiff's negligent failure to warn claim is denied. Plaintiff does not contest dismissal of all other causes of action, and therefore her strict liability and warranty claims are dismissed. The case will go trial on April 19, 2010 at 10:00 a.m. Voir dire requests, requests to charge, and proposed verdict charts are to be provided to the Court and opposing counsel by the close of business on April 12, 2010.

SO ORDERED.

Dated: New York, New York
January 27, 2010



John F. Keenan
United States District Judge